do not believe that it is possible to determine from our files when the first report of this effect first came to the attention of the FDA, we were certainly aware of them when they appeared in the literature.

Under separate cover, we have submitted additional information concerning the Wright Committee Reports. If we can supply additional information or be of further assistance, please call us.

Sincerely yours,

M. J. RYAN,
Acting Director, Office of Legislative Services.

(Whereupon, at 12:05 p.m., the committee adjourned.)

(Upon the direction of the Chairman, information pertaining to the subject of the hearings is included:)

[From the Evening Star, January 22, 1970]

WASHINGTON CLOSE-UP—ASSESSING BLAME IN 'PILL' CONFUSION

(By Judith Randal)

To this observer, the sheer, unadulterated confusion that now prevails about the safety of "the pill" is less the fault of either the pharmaceutical manufacturers or the Food and Drug Administration than the failure of government on a somewhat different score.

This is not to say that—in their eagerness for profits—the makers of oral contraceptives have been entirely candid about the risks. It has come to light during the course of current Senate hearings, for example, that as early as the first clinical trials in Puerto Rico in the 1950s, there were some sudden and unexplained deaths which were never officially reported in the medical literature and were likely traceable to the pill.

Nor can the FDA be entirely exonerated. The same Senate hearings are making it clear that the agency has not always done all it could have to inform the medical profession of the nature of the risks involved in the long-term use of chemical contraception.

The importance of the first British study linking the pill to thromboembolisms or blood clots, for instance, was deemphasized by the FDA on the grounds that British and American racial stocks are somewhat dissimilar genetically and that therefore the experience of the one country might not be applicable to the other. This strange line of reasoning with regard to foreign data of this caliber has no other precedent. Had the evidence that thalidomide caused deformities in European children been ignored, there would have been many more such children born here.

However, the real problem with the pill goes back to the days when Richard M. Nixon was vice president, and his chief, President Eisenhower, was averse to assuming leadership of the family planning movement in a world already threatened by the population explosion. (Eisenhower was to change his views after leaving office, but that is another story.)

In 1960, when oral contraceptives were licensed, government officials felt that because the subject might be politically embarrassing, birth control measures, insofar as possible, should be none of its concern. The then struggling family planning movement, therefore, had little choice but to make common cause with the profit-oriented drug companies, and the lion's share of the funding for research and development then passed by default to them.

Progestin and, particularly, estrogen, the hormones of which the many formulations of the "pill" are made, influence not only the reproductive tract, but also many other organs and tissues, including the pituitary gland, the master switch of the nervous system.

By the time of the pill's introduction, many of these influences were known. With what one of last week's witnesses called "the retropecttoscope," it is easy to see that testing should have taken them into account—particularly because oral contraceptives were designed to deal with overpopulation, a social rather than a physical ill.

A concurrent approach to this same problem was, of course, the intra-uterine device (IUD), which, whatever its other drawbacks, didn't affect the body as a whole and has since proved to be almost as effective and about twice as safe as the pill.